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Special Topic Overview

The Animal Welfare Act: From Enactment to Enforcement

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Originally enacted in 1966, the Laboratory Animal Welfare Act has been amended several times and renamed the Animal Welfare Act. Responsibility for administering the Animal Welfare Act was delegated within the United States Department of Agriculture to the Administrator of the Animal and Plant Health Inspection Service, and regulations and standards have been developed to implement the intent of Congress conveyed in the language of the Act. In our opinion, the key to compliance with the Animal Welfare Act and its regulations and standards is to have in place a proactive, progressive Animal Care and Use Program that uses the semiannual inspection and programmatic review process to improve the day-to-day management of the program. Successfully managing the inspection process has taken on new meaning in what has recently become known as the 'Age of Enforcement.' As part of this approach, the Animal and Plant Health Inspection Service made changes to the inspection process and issued an Enhanced Animal Welfare Enforcement Plan, which included the development of an Inspection Requirements Handbook. The Inspection Requirements Handbook provides inspectors with information on conducting inspections and includes as an attachment a flow chart for Enforcement Action Guidance. The chart describes 4 types of actions that may occur as part of the enforcement process and the steps that will be followed if noncompliant items are documented during an inspection.

Abbreviations: APHIS, Animal and Plant Health Inspection Service; AWA, Animal Welfare Act; NCI, Noncompliant Item; USDA, US Department of Agriculture.

The Animal Welfare Act (AWA) is intended to ensure the humane treatment of animals that are intended for research, bred for commercial sale, exhibited to the public, or commercially transported. Under the AWA, any person, as defined in the Act, with animals covered by the law must be licensed or registered and must adhere to the AWA standards of care. Here we review the history of the AWA, describe the regulatory process, emphasize the need to manage the inspection process, and describe the enforcement process currently used by the United States Department of Agriculture (USDA).

History

The law was first passed on 24 August 1966 after several years of lobbying by animal welfare organizations and allegations that pets were being sold for use in research laboratories. Originally titled the 'Laboratory Animal Welfare Act,' it became effective on 25 May 1967.[24] The stated purposes of the original Act were to: 1) protect the owners of dogs and cats from theft of such pets; 2) prevent the sale or use of dogs and cats that had been stolen; and 3) assure that certain animals intended for use in research facilities were provided humane care and treatment.

The Act authorized, "The Secretary of Agriculture to promulgate such rules and regulations, and orders as he may deem necessary to effectuate the purposes of this Act."[24] The Act prohibited the promulgation of rules, regulations, or orders that would interfere with the conduct of actual research. Determination of what constituted actual research was left to the discretion of the research facility.

The original Act covered nonhuman primates, guinea pigs, hamsters, rabbits, dogs, and cats. Humane treatment was required while the animals were at the dealers or research facility and while being transported by dealers. Dealers were required to be licensed. Research facilities that used, or intended to use, dogs or cats and either purchased them in commerce or received any federal funds were required to be registered. The Secretary also established regulations and standards for the implementation of unannounced facility inspections and for the maintenance of specific records by dealers and research institutions.

In 1970, the original Act was amended and renamed the 'Animal Welfare Act' (AWA).[4] The amended Act covered broader classes of animals and included those used in exhibitions and sold at auction and regulated any person, as defined in the Act, involved in these activities. The definition of an animal was expanded to include all warm-blooded animals. The definition of a research facility was expanded to include those institutions using covered live animals and not just dogs and cats. These facilities were required to file an annual report. In addition, civil penalties were added for refusing to obey a valid cease-and-desist order from the Secretary. The term 'handling' was added to the basic categories for which standards were to be created, and the phrase 'adequate veterinary care' was broadened to include the appropriate use of anesthetics, analgesics, and tranquilizers. The intent of the original Act to prohibit interference with research was clarified, and the Secretary was prohibited from directly or indirectly interfering with, or harassing in any manner, research facilities during the conduct of actual

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research or experimentation. The determination of when actual research was being conducted was still left to the discretion of the research facility itself.

In 1976, the AWA was amended further to enlarge and redefine the regulation of animals during transportation and to prohibit the use of animals for fighting.[5] The amended Act included all forms of commercial transportation of animals and required registration of all carriers and intermediate handlers who were not required to be licensed under the Act. In addition, the 1976 version of the AWA expanded the definition of a dealer and extended record-keeping requirements to carriers and intermediate handlers. At this time, the Secretary also promulgated regulations that specifically excluded rats, mice, birds, horses, and farm animals from the definition of an animal.

In 1985, the AWA was further amended with the passage of the Food Security Act of 1985, which contained an amendment titled 'Improved Standards for Laboratory Animals Act.'[22] This amendment required the implementation of Institutional Animal Care and Use Committees (IACUC), strengthened the standards for providing laboratory animal care, increased USDA enforcement of the Act, provided for collection and dissemination of information to reduce unintended duplication of experiments using animals, and mandated training for those who handle animals.[22] The 1985 amendment to the AWA also included the development of standards: for the "exercise of dogs,"[22] for "provision of a physical environment which promotes the psychological well-being of primates,"[22] and for limitation of multiple survival surgeries. A further standard required investigators to consult with a veterinarian in the design of experiments that have the potential for causing pain to assure the appropriate use of anesthetics, analgesics, and tranquilizers.

The 1990 amendment to the AWA was titled the 'Pet Protection Act.'[20] The regulations developed to implement this amendment defined the minimal holding period for animals in pounds and shelters that are sold to dealers and established record-keeping requirements for dealers who obtain dogs or cats from these sources. The 2002 amendment to the AWA clarified the intent of Congress in terms of the animals covered by the Act.[19] The term 'animal' in the law was redefined to match the language in the regulations. This change meant that the definition of animal in the AWA excludes "birds, mice of the genus *Mus*, and rats of the genus *Rattus*, bred for use in research,"[19] but the animals are covered when used for other purposes covered by the Act. The 2008 amendment to the AWA increased the maximal fine for violations of the AWA from $2500 to $10,000.[21] Though the maximal fine that the USDA could levy for violations was increased, the change did not make such fines mandatory.

The AWA and its Regulations

The AWA authorizes the Secretary of Agriculture to develop regulations and standards to implement the intent of Congress as conveyed in the language of the Act. The AWA can be amended through the normal legislative process by the successful passage of a bill by both the House of Representatives and the Senate and signature by the President. Such a bill could be introduced at any time, but major amendments to the AWA typically are included in the reauthorization of the Farm Bill, an omnibus bill governing federal farm and food policy covering a wide range of programs and provisions. The Farm Bill is an authorization bill and is reauthorized approximately every 5 y. The Farm Bill was last updated in 2008 and is scheduled to be reauthorized in 2012.[21] The regulations are those developed by the USDA, as the Executive Agency responsible for the enforcement of the AWA.[7]

In addition to the regulations that are developed as a result of changes to the AWA, the Secretary of Agriculture can change or add to the existing regulations through the rulemaking process governed by the Administrative Procedures Act.[1] A rule is any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.[2] An agency may issue rules only within the scope of its authorizing legislation. The USDA Animal and Plant Health Inspection Service (APHIS) must conduct rulemaking whenever it wishes to enforce a new rule. The Administrative Procedures Act requires that the proposed rule be published in the *Federal Register* to provide the public the opportunity to submit written comments. The final rule must then be published in the *Federal Register*, with an explanation of any changes that the agency has made and a response to the public comments. In publishing a final rule, an effective date for the final rule to become a regulation must be included that is at least 30 d after publication, unless the rule relieves restrictions or there is other good cause for making the rule effective earlier.[3]

The rule-making process is quite involved and time-consuming. Years may pass between the time when a need for a change in regulations is identified and actual implementation of new regulations. Once a need is identified, an analysis of the proposed rule and its effect must be prepared, along with a work plan. Under Executive Order 12866, that information must then be reviewed by the Office of Management and Budget if the rulemaking action is determined to be "significant."[17] The proposed rule is drafted, and any analyses that will be included must be completed and reviewed by USDA attorneys and the Office of Management and Budget if the proposed rule is considered to be significant. The proposed rule then is published in the *Federal Register* and undergoes a 60-d (minimum) comment period.[18]

Regulations and Standards

The Animal Welfare Regulations can be found in Title 9 of the Code of Federal Regulations.[8] Part 1 is the definition of terms and contains key definitions used in the regulations and standards. Words not defined in this part can be defined by use of a standard dictionary. Part 2 contains the regulations, which include subparts for licensing, registration, research facilities, adequate veterinary care, identification of animals, stolen animals, records, compliance with standards, and miscellaneous. Part 3 contains the standards for the day-to-day care and is divided into subparts according to species covered under the AWA. Each subpart includes specific standards that address facilities and operating practices, animal health and husbandry, and transportation. Part 4 describes the scope and applicability of the rules of practice, summary action that can be taken to suspend a license, and the stipulation process.

Subpart C of Part 2 contains the requirements for research facilities and includes sections on registration, the IACUC, personnel qualifications, the attending veterinarian and adequate veterinary care, record-keeping requirements, the annual report, federal research facilities, and miscellaneous. Each research facility has to show on inspection, and include in their annual report, assurances that professionally acceptable standards for the care, treatment, and use of animals are being used during the actual research or experimentation.[9] As part of these standards, the investigator is required to consider alternative techniques to those which might cause pain in the experimental animals.[10]

The IACUC is charged to act as an agent of the research facility in assuring compliance with the AWA. The IACUC is required to inspect all animal facilities and study areas at least once every 6 mo and to review the condition of the animals and the practices involving pain to the animals to assure compliance with the regulations and standards promulgated under the AWA.[6,11] In addition, the IACUC must review the research facility's program once every 6 mo, to assure that the care and use of the animals conforms to the regulations and standards. The IACUC must file a report of its inspection with the Institutional Official of the research facility. "Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any federal agency funding that activity."[11]

The IACUC also is required to review and approve all proposed activities involving the care and use of animals in research, testing, or teaching procedures and all subsequent significant changes of ongoing activities. As part of this review, the IACUC must evaluate procedures which minimize discomfort, distress, and pain. In addition, the IACUC must determine that a veterinarian has been consulted in planning for the administration of anesthetics, analgesics, and tranquilizers and that paralytic agents are not used except in anesthetized animals. The IACUC must determine that animals that experience severe or chronic pain are euthanized consistent with the design of the study, that the living conditions meet the species' needs, that necessary medical care will be provided, that all procedures will be performed by qualified individuals, that survival surgery will be performed aseptically, and that no animal will undergo more than one operative procedure that is not justified and approved. Methods of euthanasia must be consistent with the definition contained in the regulations.

The IACUC must assure on behalf of the research facility that the principal investigator has considered alternatives to painful procedures and that the work being proposed does not unnecessarily duplicate previous experiments. To provide assurance of the consideration of alternative to painful procedures, the IACUC must review the written narrative description provided by the investigator. This description must include the methods and sources used in determining that alternatives were not available. In reviewing proposed activities and modifications, the IACUC can grant exceptions to the regulations and standards, if they have been justified in writing by the principal investigator.

In addition to the requirements just discussed, the research facility is required to provide training to scientists, animal technicians, and other personnel involved with animal care and treatment in the following areas: 1) humane methods of animal maintenance and experimentation; 2) the concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress; 3) appropriate use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility; 4) methods whereby deficiencies in animal care and treatment are reported; and 5) utilization of services (for example, National Agricultural Library, National Library of Medicine) available to provide information.[12]

The mandated program of adequate veterinary care at research facilities includes: appropriate facilities, personnel, and equipment; methods to control, diagnose, and treat diseases; daily observation and provision of care; and guidance to personnel on the use of anesthetic, analgesic, and euthanasia procedures and pre- and postprocedural care.[13] Specific requirements for maintaining records[14] and filing annual reports[15] are included in the regulations, along with a miscellaneous section containing a variety of requirements to which a research facility must adhere.[16]

Key Requirements for Compliance

The key to compliance with the requirements of the Animal Welfare Regulations is to have in place a proactive, progressive Animal Care and Use Program that uses the semiannual inspection and programmatic review process to improve the day-to-day management of the program. Because the USDA's annual inspection process is the basis for their assessment of the institution's compliance through inspection of the facilities and institutional records, institutions should develop and implement a process for managing the inspection process and the creation and retention of records.

A May 2004 article about managing inspections contains suggestions that remain applicable today.[23] For a successful inspection, a facility should: 1) establish a defined procedure for the conduct of these inspections; 2) identify an inspection walk-through team that is familiar with the operation of the areas through which they will accompany the inspector; 3) notify key persons (such as animal care and IACUC support staff) who may be involved in the inspection; 4) determine what the inspector plans to review during the process and arrange for the availability of pertinent records and a conference room or office for the inspector to use; 5) ensure that a member of the inspection team has a detailed working knowledge of the institution's animal care and use program and knows the regulations and standards, the contents of the *Animal Care Resources Guide*,[30] and the information contained in Section of 7 of the *Research Facility Inspection Guide*.[26] This person should be prepared to ask for clarification of potential noncompliant items, discuss the issue thoroughly, clearly explain how the facility's program operates and clarify why any activity is consistent with the requirements and regulations. This person should also be familiar with the appeal process in the event that compliance issues are raised the institution considers unfounded.

Successfully managing the inspection process has taken on new meaning in the current USDA-identified 'Age of Enforcement.'[25] The inspection process historically has emphasized education; inspectors worked with institutions and their IACUC to assure the welfare of the animals in each unique registered research facility. APHIS may now be following a more rigid enforcement approach, with less latitude for repeated citations and more rapid and consistent enforcement actions.[25] As part of this approach, APHIS issued in 2010 an Enhanced Animal Welfare Enforcement Plan,[27] which included the development of an *Inspection Requirements Handbook*.[28]

As part of the Enhanced Animal Welfare Enforcement Plan, APHIS "removed 'no action' as an enforcement option and added a requirement that management [APHIS] will review enforcement actions for repeat or serious violations."[27] This change eliminates the Veterinary Medical Officer's option to accept a facility's corrective action of an existing or previous Noncompliant Item (NCI) and appears to promote a prescriptive form of the inspection process over performance-based standards.

The *Inspection Requirements Handbook* contains 2 additional items that may lead to a more rigidly enforced inspection process.[28] The first involves Repeat NCI. The word 'must' has replaced the word 'should' in referring to when an NCI is designated as a repeat item.[28] An inspector must designate an NCI as a Repeat when it involves the same section or subsection cited in a previous inspection, even if the citation involves

different animals or different portions of the facility.[28] How this change affects organizations that have a single registration but different locations in different geographical areas is still unclear. The second item is the section on Inspection Photographs. This item requires (the word 'must' is used) photographs of Direct NCI and all other NCI noted during the same inspection.[28] This is also the case for a Repeat NCI: repeat NCI and all other NCI noted during the same inspection must be photographed.[28] Photographs must also be obtained if an NCI is likely to be appealed.[28]

In the Attachments to the *Handbook*, the last 2 pages are key to understanding the enforcement process.[29] One page is an Enforcement Action Guidance flow chart that outlines the inspection process under the Risk-Based Inspection System. The second page provides additional details on the 4 actions that appear at the bottom of the flow chart.

The Enforcement Process

Responsibility for administering the AWA was delegated within the USDA to the Administrator of APHIS. Enforcement duties are the responsibility of the APHIS Deputy Administrator for Animal Care. The inspections of research facilities are conducted by the Veterinary Medical Officer working under one of the Animal Care Regional Supervisors. The Veterinary Medical Officers identify and report NCI. Any subsequent enforcement actions are handled by Investigative and Enforcement Services, whose investigators evaluate the NCI (alleged violations) and prepare case reports. If a case warrants prosecution, APHIS takes legal action, usually through an administrative law process. Many cases are closed with an official warning, but sometimes Investigative and Enforcement Services issues stipulations that may include a civil fine or other penalty. Serious cases or those involving repeat violations are submitted to an administrative law judge, who can suspend or revoke the violator's USDA license and impose a fine. If a violation is sufficiently serious, Investigative and Enforcement Services will work with the Department of Justice to build a criminal case.

The flow chart for Enforcement Action Guidance describes 4 possible follow-up actions with regard to an NCI.[29] The first is the 90-d reinspection, which takes place when a facility is making clear progress toward compliance and the inspector found only a few minor NCI (including only a few repeat NCI) and no signs of jeopardizing animals, animal health, or animal welfare being. The facility must have had no Enforcement Actions within last 3 y, and the inspector expects the facility to come into compliance. If compliance is not achieved in 90 d, the agency will proceed to other enforcement steps.

The next step in the process is the issuance of an Official Warning Letter, which notifies a person or company of an alleged violation. This notification may be issued with or without an investigation by Investigative and Enforcement Services. The reasons for issuing an Official Warning Letter include an inspector finding that a facility: is out of compliance after a 90-d reinspection, has multiple Repeat NCI, has a Direct NCI, has incomplete documentation of a serious NCI, is making slow progress toward compliance, and has had no Enforcement Actions (except 90-d reinspection) within the last 3 y.

The third step in the process is the issuance of a Stipulation: an agreement in which the USDA gives notice of an alleged violation and agrees to accept a specified penalty to settle the matter. The settlement agreement form used by Investigative and Enforcement Services requires that the penalty be paid within a designated time frame and states that the payment constitutes a waiver of the alleged violator's right to a hearing and a finding that violations of the law have occurred. Before issuing a Stipulation, Investigative and Enforcement Services must conduct an investigation. The investigation links the identification of multiple minor Repeat NCI, moderate to serious NCI, or Repeat Direct NCI with a lack of progress toward compliance. These actions have typically been taken with regard to facilities that have had previous Enforcement Actions and/or at which animal health and welfare have been compromised.

The fourth and final step in the process is prosecution by the Office of General Counsel. A Complaint from this Office gives notice to a facility of a formal allegation of possible violations of the AWA. The Complaint does not mean that the facility is guilty of these violations but serves as a notice that the facility must respond and either agree to the allegations in the Complaint or seek a hearing date before a USDA administrative law judge. The judge issues a Decision and Order, which is based on the evidence presented by APHIS and the facility. The facility has the right to appeal this decision. A copy of the Decision and Order is posted on the USDA website.[31] This process is initiated after an Investigative and Enforcement Services investigation in response to a serious NCI or Repeat Direct or multiple Direct NCI, with no progress toward compliance, where animal health and welfare have been compromised, and when the facility typically has had previous Enforcement Actions.

Summary

Since May 2010, the USDA has initiated an enhanced enforcement process for implementing the requirements of the AWA. This enhanced enforcement requires that those responsible for their facility's compliance manage a proactive, progressive animal care and use program and implement a plan to manage the inspection process. For this plan to be effective, those responsible for its implementation must have a working knowledge of the regulations and the USDA documents used in the inspection process and an understanding of the enforcement process. The information in this article and the referenced sources and website links are subject to change based on legislative, regulatory, or other agency actions. We encourage readers to keep current on legislative changes and agency actions.

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